

- Pharmacology and Therapeutics*, 78(6):689–96, 2005.
2. Benowitz, N.L., et al., "Suppression of Nicotine Intake During Ad Libitum Cigarette Smoking by High-Dose Transdermal Nicotine," *Journal of Pharmacology and Experimental Therapeutics*, 287(3):958–62, 1998.
  3. Blondal, T., et al., "Nicotine Nasal Spray With Nicotine Patch for Smoking Cessation: Randomised Trial With Six Year Follow Up," *BMJ*, 318(7179):285–8, 1999.
  4. Bohadana, A., et al., "Nicotine Inhaler and Nicotine Patch as a Combination Therapy for Smoking Cessation," *Archives of Internal Medicine*, 160(20):3128–34, 2000.
  5. Bolliger, C.T., et al., "Smoking Reduction With Oral Nicotine Inhalers: Double Blind, Randomised Clinical Trial of Efficacy And Safety," *BMJ*, 321(7257):329–33, 2000.
  6. Bullen, C., et al., "Precessation Nicotine Replacement Therapy: Pragmatic Randomized Trial," *Addiction*, 105(8):1474–83, 2010.
  7. Dale, L.C., et al., "High-Dose Nicotine Patch Therapy. Percentage of Replacement and Smoking Cessation," *JAMA*, 274(17):1353–58, 1995.
  8. Etter, J.F., et al., "Nicotine Replacement to Reduce Cigarette Consumption in Smokers Who Are Unwilling to Quit: A Randomized Trial," *Journal of Clinical Psychopharmacology*, 22(5):487–95, 2002.
  9. Etter, J.F., et al., "Postintervention Effect of Nicotine Replacement Therapy on Smoking Reduction in Smokers Who Are Unwilling to Quit: A Randomized Trial," *Journal of Clinical Psychopharmacology*, 24(2):174–79, 2004.
  10. Etter, J.F., et al., "Nicotine Gum Treatment Before Smoking Cessation—A Randomized Trial," *Archives of Internal Medicine*, 169(11):1028–34, 2009.
  11. Hajek, P., et al., "Dependence Potential of Nicotine Replacement Treatments: Effects of Product Type, Patient Characteristics, and Cost to User," *Preventive Medicine*, 44(3):230–34, 2007.
  12. Hall, S.M., et al., "Extended Treatment of Older Cigarette Smokers," *Addiction*, 104(6):1043–52, 2009.
  13. Hatsukami, D., et al., "Effects of High Dose Transdermal Nicotine Replacement in Cigarette Smokers," *Pharmacology, Biochemistry, and Behavior*, 86(1):132–39, 2007.
  14. Horst, W.D., et al., "Extended Use of Nicotine Replacement Therapy to Maintain Smoking Cessation in Persons With Schizophrenia," *Neuropsychiatric Disease and Treatment*, 1(4):349–55, 2005.
  15. Houtsmuller, E.J., et al., "Flavor Improvement Does Not Increase Abuse Liability of Nicotine Chewing Gum," *Pharmacology, Biochemistry, and Behavior*, 72(3):559–68, 2002.
  16. Hughes, J.R., et al., "A Randomized, Controlled Trial of NRT-Aided Gradual Vs. Abrupt Cessation in Smokers Actively Trying to Quit," *Drug and Alcohol Dependence*, 111(1–2):105–13, 2010.
  17. Joseph, A.M., et al., "Chronic Disease Management for Tobacco Dependence," *Archives of Internal Medicine*, 171(21):1894–1900, 2011.
  18. Lerman, C., et al., "Genetic Variation in Nicotine Metabolism Predicts the Efficacy of Extended-Duration Transdermal Nicotine Therapy," *Clinical Pharmacology and Therapeutics*, 87(5):553–57, 2010.
  19. Lindson, N. and Aveyard, P., "An Updated Meta-Analysis of Nicotine Preloading for Smoking Cessation: Investigating Mediators of the Effect," *Psychopharmacology*, 214(3):579–92, 2011.
  20. Murray, R.P., et al., "Safety of Nicotine Polacrilex Gum Used by 3,094 Participants in the Lung Health Study. Lung Health Study Research Group," *CHEST*, 109(2):438–45, 1996.
  21. Murray, R.P., et al., "Does Nicotine Replacement Therapy Cause Cancer? Evidence From the Lung Health Study," *Nicotine & Tobacco Research*, 11(9):1076–82, 2009.
  22. Newhouse, P., et al., "Nicotine Treatment of Mild Cognitive Impairment: A 6-Month Double-Blind Pilot Clinical Trial," *Neurology*, 78(2):91–101, 2012.
  23. Piper, M.E., et al., "A Randomized Placebo-Controlled Clinical Trial of 5 Smoking Cessation Pharmacotherapies," *Archives of General Psychiatry*, 66(11):1253–62, 2009.
  24. Rennard, S.I., et al., "Efficacy of the Nicotine Inhaler in Smoking Reduction: A Double-Blind, Randomized Trial," *Nicotine & Tobacco Research*, 8(4):555–64, 2006.
  25. Rose, J.E., et al., "Mecamylamine Combined With Nicotine Skin Patch Facilitates Smoking Cessation Beyond Nicotine Patch Treatment Alone," *Clinical Pharmacology and Therapeutics*, 56(1):86–99, 1994.
  26. Rose, J.E., et al., "Nicotine-mecamylamine Treatment for Smoking Cessation: The Role of Precessation Therapy," *Experimental and Clinical Psychopharmacology*, 6(3):331–43, 1998.
  27. Rose, J.E., et al., "Precessation Treatment With Nicotine Skin Patch Facilitates Smoking Cessation," *Nicotine & Tobacco Research*, 8(1):89–101, 2006.
  28. Rose, J.E., et al., "Precessation Treatment With Nicotine Patch Significantly Increases Abstinence Rates Relative to Conventional Treatment," *Nicotine & Tobacco Research*, 11(9):1067–75, 2009.
  29. Schuurmans, M.M., et al., "Effect of Pretreatment With Nicotine Patch on Withdrawal Symptoms and Abstinence Rates in Smokers Subsequently Quitting With the Nicotine Patch: A Randomized Controlled Trial," *Addiction*, 99(5):634–40, 2004.
  30. Tønnesen, P., et al., "Higher Dosage Nicotine Patches Increase One-Year Smoking Cessation Rates: Results From the European CEASE Trial," *European Respiratory Journal*, 13(2):238–46, 1999.
  31. Wang, D., et al., "Cut Down to Quit' With Nicotine Replacement Therapies in Smoking Cessation: A Systematic Review of Effectiveness and Economic Analysis," *Health Technology Assessment*, 12(2):iii-iv, ix-xi, 1–135, 2008.
  32. Wennike, P., et al., "Smoking Reduction Promotes Smoking Cessation: Results From a Double Blind, Randomized, Placebo-Controlled Trial of Nicotine Gum With 2-Year Follow-Up," *Addiction*, 98(10):1395–402, 2003.
  33. West, R., et al., "A Comparison of the Abuse Liability and Dependence Potential of Nicotine Patch, Gum, Spray and Inhaler," *Psychopharmacology*, 149(3):198–202, 2000.
  34. Zevin, S., et al., "Dose-Related Cardiovascular and Endocrine Effects of Transdermal Nicotine," *Clinical Pharmacology and Therapeutics*, 64(1):87–95, 1998.

## V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Centers for Disease Control and Prevention, "Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004," *Morbidity and Mortality Weekly Report*, 57(45):1226–1228; November 14, 2008.
2. Centers for Disease Control and Prevention, "Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 1995–1999," *Morbidity and Mortality Weekly Report*, 51(14):300–303; April 12, 2002.
3. Centers for Disease Control and Prevention, "Quitting Smoking Among Adults—United States, 2001–2010," [serial online], *Morbidity and Mortality Weekly Report*, 60(44):1513–1519; November 11, 2011.

Dated: March 26, 2013.

**Peter Lurie,**

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07528 Filed 4–1–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Request For Public Comment: 60-Day Proposed Information Collection: Indian Health Service Medical Staff Credentials And Privileges Files

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

**Proposed Collection**

*Title:* 0917–0009, “Indian Health Service Medical Staff Credentials and Privileges Files.” *Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917–0009, “Indian Health Service Medical Staff Credentials and Privileges Files.” *Form Numbers:* 0917–0009. *Need and Use of Information Collection:* This collection of information is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities. The IHS operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers including: Physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, audiologists, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become

medical staff members, depending on the local health care facility’s capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: (1) Health care providers applying for direct employment with IHS; (2) contractors who will not seek to become IHS employees; and (3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Centers for Medicare and Medicaid Services, the Joint Commission, and other accrediting organizations require health care facilities to review, evaluate and verify the credentials, training and experience of medical staff applicants prior to granting medical staff privileges. In order to meet these standards, IHS health care facilities require all medical staff applicants to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them. This information is then verified with references supplied by the applicant and may include: former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, the Joint Commission standards require that a review of the medical staff be conducted not less than

every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is a Joint Commission requirement. Prior to the establishment of this Joint Commission requirement, the degree to which medical staff applications were maintained at all health care facilities in the United States that are verified for completeness and accuracy varied greatly across the Nation.

The application process has been streamlined and is using information technology to make the application electronically available on the Internet. The application may be found at the IHS.gov Web site address: [http://www.ihs.gov/IHM/index.cfm?module=dsp\\_ihm\\_pc\\_p3c1\\_ex#ManualExhibit3-1-A](http://www.ihs.gov/IHM/index.cfm?module=dsp_ihm_pc_p3c1_ex#ManualExhibit3-1-A).

*Affected Public:* Individuals and households. *Type of Respondents:* Individuals.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of annual number of responses, Average burden per response, and Total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per Respondent	Average burden hour per response*	Total annual burden hours
Application to Medical Staff .....	570	1	1.00 (60 mins) ..	570
Reference Letter .....	1710	1	0.33 (20 mins) ..	570
Reappointment Request .....	190	1	1.00 (60 mins) ..	190
Ob-Gyn Privileges .....	20	1	1.00 (60 mins) ..	20
Internal Medicine .....	325	1	1.00 (60 mins) ..	325
Surgery Privileges .....	20	1	1.00 (60 mins) ..	20
Psychiatry Privileges .....	13	1	1.00 (60 mins) ..	13
Anesthesia Privileges .....	15	1	1.00 (60 mins) ..	15
Dental Privileges .....	150	1	0.33 (20 mins) ..	50
Optometry Privileges .....	21	1	0.33 (20 mins) ..	7
Psychology Privileges .....	30	1	0.17 (10 mins) ..	5
Audiology Privileges .....	7	1	0.08 (5 mins) ....	1
Podiatry Privileges .....	7	1	0.08 (5 mins) ....	1
Radiology Privileges .....	8	1	0.33 (20 mins) ..	3
Pathology Privileges .....	3	1	0.33 (20 mins) ..	1
<b>Total .....</b>	<b>3,089</b>	<b>.....</b>	<b>.....</b>	<b>1,791</b>

\*For ease of understanding, burden hours are provided in actual minutes. There are no capital costs, operating costs and/or maintenance costs to respondents.

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry

out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time

needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate is logical; (e) ways to enhance

the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Send Comments and Requests for Further Information:** For the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Paul R. Fowler D.O., J.D., Risk Management Officer, 801 Thompson Avenue, TMP, Suite 331, Rockville, MD 20852, call non-toll free (301) 443-6372, send via facsimile to (301) 594-6213, or send your email requests, comments, and return address to: [paul.fowler@ihs.gov](mailto:paul.fowler@ihs.gov).

**Comment Due Date:** Your comments regarding this information collection is best assured of having full effect if received within 60 days of the date of this publication.

Dated: March 26, 2013.

**Yvette Roubideaux,**

Director, Indian Health Service.

[FR Doc. 2013-07596 Filed 4-1-13; 8:45 am]

BILLING CODE 4165-16-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; Evaluation of the Brain Disorders in the Developing World Program of the John E. Fogarty International Center**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the John E. Fogarty International Center, National Institutes of Health (NIH), will publish periodic summaries of proposed

projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**To Submit Comments and for Further Information:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Rachel Sturke, Fogarty International Center, National Institutes of Health, 16 Center Drive, Building 16, Room 202, Bethesda, MD 20892, or call non-toll-free number 301-496-1491, or Email your request, including your address to: [sturkerachel@mail.nih.gov](mailto:sturkerachel@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**Comment Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**Proposed Collection:** Evaluation of the Brain Disorders in the Developing World Program of the John E. Fogarty International Center, 0925-New, Fogarty

International Center (FIC), National Institutes of Health (NIH).

**Need and Use of Information Collection:** This study seeks to evaluate the management, effectiveness, and outcomes of the Brain Disorders in the Developing World extramural research program administered by the John E. Fogarty International Center of the NIH. The purpose of the Brain Disorders in the Developing World Program is to develop collaborative research and capacity building projects on brain disorders throughout life relevant to low- and middle-income countries. Awardees are expected to develop innovative projects that contribute to the long-term goal of building sustainable research capacity in nervous system function and impairment throughout life. Between FY 2003 and 2012, a total of 132 awards were made under the Brain Disorders program, and the total investment by Fogarty and its partners at NIH has been approximately \$75 million. The findings of this evaluation study will provide valuable information concerning: (1) Whether and how the program has met its goal of supporting research and research capacity-building on brain disorders in low- and middle-income countries; (2) the extent to which the program as implemented functions efficiently and effectively; (3) the extent to which the program is consistent with the strategic priorities of Fogarty and its partners at NIH; (4) opportunities to improve upon the current implementation of the program if NIH chooses to continue supporting it; and (5) models, best practices, and lessons learned that may be applicable to other NIH programs, now and in the future.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 151.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Awardee Interviews (LMIC) .....	Researchers .....	30	1	1	30
Awardee Interviews (US) .....	Researchers .....	30	1	1	30
Trainee Interviews .....	Researchers .....	15	1	1	15
Awardee Survey (LMIC) .....	Researchers .....	115	1	20/60	38
Awardee Survey (US) .....	Researchers .....	114	1	20/60	38